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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,825	07/17/1998	CHRISTIAN GRONHOJ LARSEN	GRONHOJ-LARS	1107

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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/17/2002 30

Please find below and/or attached an Office communication concerning this application or proceeding.

Rk copy

Office Action Summary	Application No. 09/101,825	Applicant(s) Larsen et al
	Examiner Fozia Hamud	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 27, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-22, 24-41, 49-53, 57, 59, 61, 63, and 65-82* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *18-22, 24-41, 59, 63, and 65-82* is/are allowed.

6) ☒ Claim(s) *49-53, 57, and 61* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Receipt of Applicant's arguments filed in Paper No.28, on 27 September 2002 is acknowledged..

2. The Terminal Declaimer filed, in Paper No.29, on 27 September 2002 has been entered.

3. The following previous rejections and objections are withdrawn in light of Applicants amendments filed in Paper No:28 and 24 filed on 09/27/02.

(I) The obviousness-type double patenting rejection of claims 18-22, 24-41, 49-53, 61, 63, 65-79 and 80-82 as being unpatentable over claims 1-39 of U.S. Patent No. 6,159,937.

Rejoinder of Claims 57 and 59

4a. Claim 18 (from which claim 41 is dependant) is directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 57 and 59 directed to the processes of using the patentable product in treating cancer and arthritis, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 57 and 59 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Thus claims 18-22, 24-41, 49-53, 57, 59,61, 63, 65-79 and 80-82 are pending and under consideration.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 49, 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating arthritis, pancreatitis and ARDS like syndrome, by administering to a subject in need of said treatment a pharmaceutically effective amount of the non-naturally occurring polypeptide recited in instant claim 18 , does not reasonably provide enablement a method of "all" possible diseases treatable by a substance which has the properties recited in a-k of claim 49, or a method of treating cancer, by administering to a subject in need of said treatment a pharmaceutically effective amount of the non-naturally occurring polypeptide recited in instant claim 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 49 which recites "a method of treating a disease which is treatable by a substance which has at least one of the properties recited in claim 49, (a-K)..", what is claimed is a method of treating "all" possible diseases that are treatable by a substance that displays the properties recited in a-k of claim 49, however, the instant specification demonstrates that IT9302, inhibits the production of IL-8, in a dose dependant manner and that IT9302 also induces the production of IRAP, (see page 37, lines 6-30). The instant specification demonstrates that the synthetic peptide of the instant invention has dose-dependent inhibitory effects on pro-inflammatory processes, including IL-8 production and monocyte and T cell migration. Furthermore, instant specification shows that the synthetic peptide of the instant invention modulates TNF-alpha production and inhibits LPS

induced leukopetinia. Thus, instant specification clearly shows that the peptide of the instant invention can be used in treating inflammatory diseases, such as pancreatitis, ARDS like syndrome and arthritis. Therefore, while instant specification is enabling for a method of treating arthritis, pancreatitis and ARDS like syndrome, it does not enable for a method of treating all possible diseases that might be treatable by a substance that displays the properties recited in a-k of claim 49, because one of ordinary skill in the art would not be able to predict if the peptide of the instant invention would be effective in treating "all" possible diseases t that are treatable by a substance that displays the properties of claim 49, a-k. With respect to claim 57 instant specification does not disclose a method of treating cancer by administering to a subject suffering from cancer an effective amount of the peptide of the instant invention. Applicants have not shown that the nonopeptide of instant invention is effective against cancer, and if so, which types of cancer. Instant specification establishes no nexus between cancer and the nonopeptide of the instant invention. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant application, instant specification establishes a link between the peptide of the instant invention and only a method of treating **arthritis, pancreatitis and ARDS like syndrome**. However, the skilled artisan would not

be able to predict whether the peptide of the instant invention would be effective against cancer. Furthermore, there is no guidance that the peptide of the instant invention would be effective against "all" possible diseases that are treatable by a substance that displays the properties recited in claim 49, a-k. Claim 49 encompasses an infinite number of diseases, and one ordinary skill in the art can not extrapolate from the teachings of the instant specification that the peptide of the instant invention can be used to treat each and every disease that can be treated by a substance that displays the properties recited in claim 49 a-k. Likewise, one of ordinary skill in the art can not extrapolate from the teachings of the instant specification that the peptide of the instant invention can be used to treat cancer, because instant specification does not establish a link between the peptide of the instant invention and cancer. Cancer is not one disease, it is a very complex condition which encompasses various types of malignant neoplasms, and all cancers are not caused by the same culprits and are not treatable by the same agents.

Therefore, Applicants are only **enabling for a method of treating arthritis, pancreatitis and ARDS like syndrome, by administering to a subject in need of said treatment a pharmaceutically effective amount of the non-naturally occurring polypeptide recited in instant claim 18.**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 49, 51-53, 57, 59 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 49 recites the limitation "a method of treating a disease which is treatable by a substance which has at least one of the properties recited in claim 49, (a-K)..", which renders the claim indefinite, because the metes and bounds of the claim can not be ascertained, since no specific disease is recited. Reciting the specific diseases that can be treating by a substance which has at least one of the properties recited in claim 49, (a-K) would obviate this rejection.

Claims 51-53, 57-59, 61 are rejected 35 U.S.C. § 112, second paragraph, insofar as they depend on claim 49.

Conclusion

7a. Claims 18-22, 24-41, 63, 65-79 and 80-82 are allowable.

7b. Claims 51-53, 59 and 61 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday from 6:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
16 December 2002

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600